UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: State of Montana v. Abbott Labs., Inc., et al., 02-CV-12084-PBS State of Nevada v. American Home Products Corp., et al., 02-CV-12086-PBS County of Suffolk v. Abbott Laboratories, Inc., et al., 01-CV-12257-PBS	

UNITED STATES' REPLY BRIEF AS AMICUS CURIAE

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The Defendants raise several issues in their response to the Government's *amicus* brief. Again on behalf of the Secretary of Health and Human Services (Secretary), the United States Department of Justice addresses some of those issues.

I. The Presumption Against Federal Preemption Of State Law Applies In This Case

The Government's initial brief pointed out that the traditional presumption against federal preemption applies here because the Medicaid program, including the drug rebate program, exemplifies "coordinate state and federal efforts [acting] . . . within a complementary administrative framework . . . in pursuit of common purposes[.]" See N.Y. Dep't of Soc. Servs. v. Dublino, 413 U.S. 405, 421 (1973). Contrary to the Defendants' suggestion, Congress did not pass the rebate statute to advance some uniquely federal interest, but to help reduce state Medicaid drug expenditures. See H.R. REP. NO. 101-881, at 96-8 (1990), U.S.C.C.A.N. 1990, 2017, 2108-2110; see also PhRMA v. Thompson, 251 F.3d 219, 225 (D.C. Cir.2001). Congress accomplished this, in part, by establishing a rebate mechanism that would accord the states the benefit of the best price in the marketplace. While certainly assigning the federal government the laboring oar in administering the rebates, states also play an important role in implementing the rebate program.[1] Congress also advanced the objective of reducing Medicaid drug costs by giving the states the flexibility and tools to pursue additional rebates. States may, for example, negotiate separate or supplemental rebate agreements with drug manufacturers for additional rebates in addition to the national rebates. See 42 U.S.C. §1396r-8(a)(4); PhRMA v. Thompson, 259 F.Supp.2d 39, 68 (D.D.C. 2003), aff'd, 2004 WL 690497 (D.C. Cir. 2004). States may also

[1] For example, states are responsible for determining the total number of units of each dosage form and strength paid for under the State plan in the rebate period, 42 U.S.C. § 1396r-8(c), and resolving any disputes with the manufacturers over the units reimbursed for the quarter.

establish prior authorization programs and formularies, 42 U.S.C. §§ 1396r-8(d)(1)(A), (d)(1)(B)(iv), and use those programs to encourage manufacturers to enter supplemental rebate agreements. See Letter from D. Smith, Dir. of Center for Medicaid and State Operations, Centers for Medicare & Medical Services, to all State Medicaid Dirs. 2 (Sept. 18, 2002) (Attachment 1).[2] Although the Defendants shrug off the import of these rebate statute features as "not at issue," Defs.' Br. at 4, they are plainly relevant as they reflect a "complementary administrative framework . . . in pursuit of common purposes." Dublino, 413 U.S. at 421.

Given that so much of the rebate program is designed specifically to facilitate state efforts to control their Medicaid drug costs, it is disingenuous to argue that the federal government has a "unique" or "exclusive" interest in the proper functioning of the rebate program generally, or the accuracy of the manufacturer average manufacturer prices (AMPs) or best prices specifically. Rather, given the important state interests at stake, the historical enforcement role that states have played against Medicaid fraud, see 42 U.S.C. §§ 1396a(a)(25), 1396a(a)(61), and 1396b(q)(3), and the role that states are clearly expected to play in controlling

[2] As the Director of the Center for Medicaid and State Operations stated in that letter:

> States may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients. . . . A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with those provisions as well as the paramount purpose of the drug rebate provisions which is to reduce the costs to the Medicaid program. . . . The [Social Security] Act affords the States broad authority and flexibility to implement a prior authorization program in order to secure cost savings for the Medicaid program.

Letter from D. Smith, at 2.

their Medicaid drug costs,[3] it is far more reasonable to presume against federal preemption of state law in this context absent some clear expression of congressional intent.

II. The Defendants Fail To Demonstrate That Federal Preemption Is Warranted

The Defendants have yet to provide a credible basis for the Court to dispense the "strong medicine" of federal preemption. See PhRMA v. Concannon, 249 F.3d 66, 75 (1st Cir. 2001); Grant's Dairy--Maine, LLC v. Comm'r of Maine Dept. of Agriculture, Food & Rural Resources, 232 F.3d 8, 18 (1st Cir. 2000). The Defendants fail, for example, to provide a concrete instance where a state law best price claim at issue in this matter actually conflicts with federal law. At the outset, neither the Massachusetts nor Montana/Nevada allegations cited by the Defendants, Defs.' Br. at 11, conflict on their face with the rebate statute or an agreement. Moreover, the purported inconsistency between those allegations is actually a red herring arising from the pleadings by Montana and Nevada at this early stage of the litigation. Massachusetts alleges that the defendants, including Warrick, understated their AMPs. See Mass. Compl. ¶ 79. Meanwhile, Montana and Nevada allege that the defendants, including Warrick,

> did not report the actual Best Price or "average manufacturer's price," but instead (i) reported higher prices and (ii) excluded discounts and other inducements offered to physicians and providers that resulted in lower prices than the prices reported to the Medicaid Program.

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[3] Notably, the Secretary recently acknowledged the role of state enforcement efforts under the rebate program in a proposed rule cited by the Defendants. In that rule, the Secretary stated:

> [W]e believe that due to potential fraud and abuse violations and litigation, a 10-year recordkeeping requirement will be more appropriate and sufficient to ensure a Federal standard with regard to the Medicaid drug rebate program that will not hinder the activities of Federal and State law enforcement officials."

Medicaid Program: Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program, 69 Fed. Reg. 508, 510 (Jan. 6, 2004) (emphasis added).

Mont. 2d Am. Compl. ¶ 674; Nev. Am. Compl. ¶ 473 (emphasis added). While the Defendants chose to focus on the AMP portion of the allegation in order to create an apparent conflict, the context of the allegation reveals that Montana and Nevada actually meant to address only best price in that paragraph. This can be reasonably inferred both from the prior three paragraphs, which focus on the best price, Mont. 2d Am. Compl. ¶¶ 671-673, as well as the nature of the fraud alleged, which was that the defendants sought to underpay their Medicaid rebate obligations.[4] Similarly, while "educational grants" are not expressly enumerated under 42 U.S.C. § 1396r-8(c)(1)(C)(i) or the rebate agreement, such grants may have to be accounted for if they were merely disguised discounts or price adjustments.[5] The Defendants' cramped reading of their rebate obligations is insufficient to establish an actual conflict, much less a "physical impossibility." See Boggs v. Boggs, 520 U.S. 833, 844 (1997); Phillip Morris Inc. v. Harshbarger, 122 F.3d 58, 68 (1st Cir. 1997).

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[4] Because the unit rebate amount is typically the difference between the AMP and the best price, manufacturers have an incentive under the rebate program to report "higher [best] prices" and to "exclude discounts" from their *best price* calculations, not their AMPs, in order to minimize their rebate payment obligations. The Defendants' emphasis on AMP is simply unwarranted and fails to create a genuine conflict.

[5] As CMS noted:

> Except for the explicitly listed exclusions in the rebate agreement and in section 1927 of the Social Security Act, and, in accordance with sections I(a) and I(d) of the rebate agreement, AMP and best price data ". . . must be adjusted by the Manufacturer if . . . other arrangements subsequently adjust the prices actually realized." Thus, we consider any price adjustment which ultimately affects the price actually realized by the manufacturer as "other arrangements" and, as required by the rebate agreement, included in the calculations of AMP and best price.

CMS Medicaid Drug Rebate Program Release No. 14, at 2. See Attachment 2.

The Defendants' continued attempts to shoehorn this case into Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2000), also remain unconvincing. While arguing that state law best price claims will inevitably interfere with agency determinations regarding best price, Defs.' Br. at 14, or the appropriate imposition of penalties, id. at 15, the Defendants still paper over the fact that the Secretary plays a fundamentally different role in administering the rebate program than the Food and Drug Administration (FDA) does in evaluating and approving medical devices. Under the "Section 510(k)" process at issue in Buckman, the FDA is committed to evaluating applicant's extensive submissions and determining whether the proposed medical device is "substantially equivalent" to a predicate device already in commercial distribution before allowing the applicant device to be marketed or distributed. Buckman, 531 U.S. at 345-46. In contrast, the Secretary, while certainly retaining audit and survey authority, is not statutorily responsible for evaluating or approving every reported AMP or best price before setting the URA. Similarly, unlike the pricing concerns at issue in this case, an approval by the FDA represents a careful and deliberate balancing of competing statutory objectives, namely ensuring the safety and efficacy of medical devices while not intruding upon the discretion of health care professionals. Id. at 348-350. Under these circumstances, the Buckman Court's driving concern over preserving the full force of the FDA's substantive judgments, id. at 348, is simply not as pronounced an issue in this case.

Similarly, the Defendants have not shown that allowing Montana and Nevada to proceed with their best price claims will upset the delicate balance of, or present an obstacle to, federal statutory objectives. One of the paramount objectives of the rebate program is to reduce state Medicaid drug costs. Thompson, 251 F.3d at 225. To the extent that Montana or Nevada

successfully demonstrates that a manufacturer failed to accurately calculate or report its AMP or best price in accordance with the rebate statute or agreement, such a result would directly advance federal objectives. Nor have the Defendants demonstrated how the present state actions would "dramatically increase the [manufacturers'] burdens." Buckman, 531 U.S. at 341. In Buckman, the Court found it "highly likely" that state law fraud actions would create an "extraneous pull" on the regulatory scheme by, for example, either deterring applicants from applying or encouraging them to submit too much information and thereby slowing down the approval process. Id. at 350-51, 353. The Defendants have not argued, much less suggested, that state law best price actions as presently alleged in this case will deter manufacturers from participating in the drug rebate program. Nor have the Defendants explained how the state law actions would alter how manufacturers calculate their AMPs or best prices.[6] While the Defendants speculate that states will interpret "best price" or AMP in wildly divergent ways, there is simply nothing in the record in this case to suggest, much less prove, that states will be unable to construe the rebate statute or agreement in manner consistent with congressional and agency intent. While the Government does not discount completely the possibility that a state

[6] In response to the Defendants' concerns regarding inconsistent court results, 42 U.S.C. §1396r-8(c) requires the manufacturers to submit, each quarter, a single report to CMS listing their "best price" as that term is defined in 42 U.S.C. §1396r-8(c)(1)(C). As a practical matter, should an ambiguity arise as to the meaning of this requirement as a result of differing courts' interpretations of 42 U.S.C. §1396r-8(c)(1)(C), the Defendants have numerous avenues open to them for a determination of their uniform national obligation, including seeking clarification directly from CMS. See CMS Medicaid Release No. 14, at 2 (describing agency process for evaluating revised AMP calculation methodologies). In any event, this Court has already rejected, in the context of the non-state plaintiffs' claims in this action, the argument that differing state court interpretations of federal law necessarily creates a conflict for purposes of a preemption analysis. In re Pharm. Indus. Average Wholesale Price Litigation, 263 F. Supp. 2d 172, 188-89 (D. Mass. 2003).

could one day impose a rebate obligation contrary to the rebate statute or agreement, such conflicts are better resolved case-by-case based on the specific facts and not through the wholesale preemption of all state law best price claims.

CONCLUSION

For the foregoing reasons, Montana and Nevada's state law best price claims should not be preempted.

Respectfully submitted,

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Dated: April 23, 2004

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was served upon all counsel of record who are not registered to receive electronic notification through the court's Electronic Case Filing system by first class mail, postage prepaid, on this date.

Date: April 23, 2004

/s/ George B. Henderson, II
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